UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	)	MD 15-02641-PHX-DGC
Lisa Hyde and Mark Hyde, a married couple,	)	Phoenix, Arizona **September 20, 2018**
Plaintiffs,	)	
v.	)	CV 16-00893-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation, and Bard Peripheral Vascular, an Arizona corporation,	)	
Defendants.	)	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 3 - P.M. SESSION

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P R O C E E D I N G S

(Jury not present.)

(Proceedings resumed at 1:12 p.m.)

THE COURT: Counsel, there were matters you wanted to raise?

MR. O'CONNOR: Yes, Your Honor. I have drafted a jury instruction and met with counsel, and they have agreed to the language. I can read it to you. We've agreed to language on that instruction about other litigation. I can read it to you and then give it to you if you'd like.

THE COURT: Well, that's fine. Why don't you read it into the record.

MR. O'CONNOR: What we've agreed to, and Ms. Helm was kind enough to agree to this: There were questions about litigation against another medical device company called Cook. This is the only lawsuit that Lisa and Mark Hyde are involved in. They are not involved in other filter litigation.

THE COURT: All right.

MR. O'CONNOR: Would you like it?

THE COURT: You agreeable to that, Ms. Helm?

MS. HELM: I am, Your Honor.

THE COURT: Yeah. I'll give that to the jury when we get them in here.

MR. O'CONNOR: Want to see if you can read my handwriting?

THE COURT: Yeah. I can read it, I think. So I'll give that.

MS. REED ZAIC: Just a -- literally just thought of this because it was sitting on my table. We are going to play a video today if we can squeeze it in; if not, tomorrow. But it's going to be the first video where we read an introduction and then we're going to have that conversion of deposition exhibits to trial exhibit numbers. I didn't know if you wanted me to explain that to the jury or if you want to explain that before I move them in.

THE COURT: This will be where you'll give the deposition exhibit number and then you'll give the trial exhibit number so the jury --

MS. REED ZAIC: The corollary, yes.

THE COURT: How many are there?

MS. REED ZAIC: In this one, there are only five.

THE COURT: Okay. And I will explain to the jury that's what we're doing. Are you then going to move all of those in --

MS. REED ZAIC: Yes.

THE COURT: -- before the witness testifies?

Okay. Let's move them in so there's a record of it coming in. If you want to add something to what I say, feel free, but I'll explain that to them.

MS. REED ZAIC: Okay. Thank you.

THE COURT: Anything else we need to raise?

MR. ROGERS: No, Your Honor.

THE COURT: Okay. Let's bring in the jury.

You can come back up, Dr. McMeeking.

(Jury present.)

THE COURT: Please be seated. Welcome back, ladies and gentlemen.

I'll wait for everybody to get their earpieces in.

Let me say one thing to you before we resume with the cross-examination of Dr. McMeeking. Before the lunch hour, there were questions about litigation against another medical device company called Cook. This case that you're hearing is the only lawsuit that Lisa and Mark Hyde are involved in. They are not involved in other filter litigation.

MS. HELM: Thank you, Your Honor.

THE COURT: Go ahead.

ROBERT MCMEEKING, PH.D.,

called as a witness herein by the plaintiffs, having been previously duly sworn or affirmed, resumed the stand and continued to testify as follows:

CROSS-EXAMINATION (Continued)

BY MS. HELM:

Q. Dr. McMeeking, in your work in the Cook litigation, you have been retained by either the plaintiffs or the attorneys representing the plaintiffs in those cases; correct?

A. That's correct.
Q. Okay. And you have offered opinion in those -- in those cases that the Cook filters are defective; correct?
A. That's correct.
Q. Okay. And one of the opinions you offered is that the Cook filter tilts more than any other filter that you've examined; correct?
A. That's correct.
Q. Okay. I want to talk very, very briefly about the calculations you did in this case. You did three sets of calculations; correct?
A. I think I did more, but I did a handful of calculations.
Q. And one of the calculations you did was about the arm strain in the Recovery filter; correct?
A. That's correct.
Q. And you only tested or you only analyzed one arm; correct?
A. That's -- I analyzed one arm as it represented all six.
Q. And then another analysis you did concerned tilt in a G2 filter; correct?
A. That's correct.
Q. And the third analysis you did also dealt with tilting calculations; correct?
A. That's correct.
Q. Okay.
A. But may I point out, I did more calculations than the ones

you've mentioned.
Q. But those are three of the main calculations that you performed; correct?
A. No. I -- some of the main calculations I calculated were finite element calculations for both the G2 and the Recovery in regard to fatigue strains and calculations on a piece of paper for the same purpose.
Q. Okay. You understand that when Ms. Hyde's filter was retrieved by Dr. Kuo, he retrieved the entire filter plus the strut that had fractured; correct?
A. That's correct.
Q. Okay. And so when he retrieved it, the filter had 11 struts, and then he retrieved the 12th strut separately; correct?
A. That's my understanding.
Q. Okay. You do not have Ms. Hyde's filter or the fractured strut to examine, do you?
A. I do not.
Q. And you would agree with me that in order to determine whether that strut fractured from a fatigue failure, you need to examine the strut?
A. Well, the most direct way of determining whether it fails by fatigue failure is to look at the surfaces that have broken on the parts involved. However, the correlation of so many filters failing by fatigue is an indication that her filter

failed by fatigue fracture as well.
Q. You're making that assumption?
A. I'm making that inference.
Q. Okay. Because you have not examined the filter?
A. Because I have not examined the filter.
Q. Okay. You also offered opinions that Ms. Hyde's filter fractured as a result of perforation resulting in fracture; correct?
A. That's correct.
Q. Okay. You don't know if the strut that fractured had previously perforated her IVC, do you?
A. I do not know that.
Q. You also mentioned in this case that the -- that the failures contributed or caused -- that the failures that you've identified -- migration, tilt, perforation, and fracture -- all occurred in Ms. Hyde's filter; correct?
A. That's correct.
Q. Okay. Are you aware that Dr. Hurst testified yesterday that the degree of tilt of Ms. Hyde's filter was somewhere between 2 and 4 degrees?
A. I'm aware of the fact he said it was a very small amount of tilt. I didn't know those exact numbers.
Q. And you're also aware that he testified that her migration, if any, was around, at the most, 2 millimeters?
A. Again, I was aware that it was a very small amount of

migration. I did not know that specific number.
Q. Okay. In relying on information about Ms. Hyde, you have to rely on information from others; correct? You're not a medical doctor?
A. That's correct.
Q. And you've relied on information from Dr. Hurst and Dr. Muehrcke; correct?
A. That's correct. I also looked at some medical records and some imaging for her filter.
Q. And would you agree with me that at the time of your deposition in this case, you did not know whether the fractured strut was an arm or a leg?
A. I -- I looked at my deposition, and I believe I said that the arm had broken but that struts had perforated. And I didn't know whether the struts that had perforated were either arms or legs. That was the meaning of what I said.
Q. Okay. You don't have any information on your own or from Dr. Hurst or Muehrcke about the environment, the specific environment in Ms. Hyde's vena cava, do you?
A. Not specific information about it.
Q. You don't know what her blood flow was; correct?
A. Correct.
Q. You don't know what her respiratory rate was?
A. No, I do not know that.
Q. You don't know what her experiences were with Valsalva, the

term you used; correct?
A. Correct.
Q. You don't know -- Ms. Hyde has sleep apnea. You don't know how that impacted her filter, do you?
A. No, I do not know that.
Q. You didn't try to determine at all how her anticoagulant use may have impacted her filter, did you?
A. No, I did not.
Q. And neither Dr. Hurst nor Dr. Muehrcke offered you any of that information, did they?
A. I didn't ask for it and they didn't offer it to me.
Q. You didn't investigate anything specific about Ms. Hyde's anatomy or her medical conditions; correct?
A. That's correct.
Q. I want to stand corrected. I said that Dr. Hurst said that it had migrated approximately 2 millimeters. He actually said 5. So I don't want to -- I don't want to have misrepresented his testimony.
A. It's still a number I did not know, so...
Q. Pardon me?
A. It's still a number I did not know, so...
Q. Okay. And my last question is: As you sit here today, within a reasonable degree of engineering certainty, you cannot tell this jury whether your proposed ideas of caudal anchors, penetration limiters, or a change in the angle of the struts

coming out of the chamfer would have reduced or prevented Ms. Hyde's injury, can you?

A. I would say that based on an engineering assessment, which contains a reasonable degree of certainty, that I believe -- it is my assessment that those features would have improved the performance of her filter.

Q. And that's based on your assessment. It's not based on any design drawings, any calculations, any finite element analysis, any prototype or any testing; correct?

A. That's correct.

MS. HELM: Thank you. Nothing further.

THE COURT: Redirect?

MR. O'CONNOR: Yes, Your Honor.

REDIRECT EXAMINATION

BY MR. O'CONNOR:

Q. Dr. McMeeking, you've reviewed how many Bard documents?

A. Hundreds, if not thousands.

Q. Now, Mrs. Hyde's filter, as you know, was February of 2011. Are you aware of that?

A. I'm aware of that, yes.

Q. Did you come across any information in the Bard documents you looked at where Bard knew about and had been considering caudal anchors long before 2011?

A. Yes, I did.

Q. That's a feature --

MS. HELM: Your Honor, excuse me. This exceeds the scope of the cross-examination.

THE COURT: Overruled.

BY MR. O'CONNOR:

Q. And the same question: Had Bard, before Mrs. Hyde received her filter, known about penetration limiters?

A. Yes, they did.

Q. And certainly did you expect that Bard would know how the Simon Nitinol filter behaved?

A. Yes. They would be aware of its performance and attributes.

Q. And in -- the questions about other filters, you haven't done any type of analysis yourself to compare to what extent Bard compares to other filters, have you?

A. I have not done such assessments.

Q. But you do understand there is evidence?

A. I do, yes.

Q. And in your -- from what you have seen with Bard filters, are Bard -- the filters that you've seen in Bard, do they show in a single filter often more than one failure mode?

A. Yes. They often have all of the failure modes I've been discussing.

Q. And that question about what you've done in Cook, that's a different filter than this filter; is that right?

A. That's correct.

Q. And the filter that you were asked about made by this other company, Cook, that you have rendered opinions on, what happened to that filter?
A. It was taken off the market.
Q. Now, you were asked questions about being retained as an expert. But I want you to tell the jury, is there anything differently you would have been -- done if this was a medical device company that retained you?
A. No. I did everything in the same way that I work when I'm consulting for a medical device company. I review their documents. I look at their bench testing. I don't do the bench testing myself. I do calculations of both a pencil and paper type and finite element calculations for them. And I review their designs and make suggestions about how to improve designs and the testing that the products are put through.
Q. And you -- I think you told us you're a design and materials engineer?
A. Yeah.
Q. I can't remember --
A. I'm a mechanical engineer, and I'm a materials scientist and materials engineer.
Q. Did you do all the work in this case that engineers in your field would do?
A. Yes, I did.
Q. And by the time you did your calculations, did you feel

there was any need for bench testing?
A. No, because I was convinced by my calculations and also by reviewing Bard documents, which had some bad examples of testing in them, that there was no need to carry out bench testing or ask someone else to do it.
Q. And this question to you about microscopic evaluation, have you evaluated cases involving filter failures where there have been no microscopic evaluations?
A. Yes. I've evaluated cases where the filter was not available for inspection.
Q. Is there any question at all that the arm came off of the filter and migrated into the right ventricle of Mrs. Hyde's heart?
A. There's no doubt about that. I saw the image myself from Dr. Kuo.
Q. And based upon your calculations and the work you've done with Bard filters, did you determine to a reasonable degree of engineering probability that the most probable cause was what? Fracture?
A. Yes.
MS. HELM: Object, Your Honor. It's leading.
THE COURT: Sustained.
BY MR. O'CONNOR:
Q. Let me start another way.
From your perspective as an engineer, did you do

everything you needed to do to determine that the reason that -- how that piece of the heart -- why it got to the ventricle?

A. I did what I needed to do to determine that it was a fatigue failure that caused the fracture and led to the arm migrating to her heart.

Q. And you were asked about all these other so-called hundreds of tests that Bard conducted. Do you recall those questions?

A. Yes.

Q. I mean, are there many, many other tests that have nothing to do with failure modes?

A. That's correct. I read many, many documents that describe those other tests, and I even looked at tests, animal tests and clinical evaluations. But the ones I needed to focus on came to my attention because I identified the failure modes and the problems, and I focused on those documents that were relevant to that situation, the documents that discussed the tests and the calculations that were focused on those failure modes. I didn't want to take the jury's time to discuss all these other tests because they were not relevant.

Q. Were they the tests that pertained directly to the failure modes that Bard was aware of?

A. Those -- the tests that I did describe to the jury are the ones that were directly related to those failure modes, or the tests that didn't exist were those that would have related to

those failure modes.
Q. And you told the jury both about the tests you reviewed, the inadequacy, and did you talk about today the tests that should have been done that weren't?
A. That's correct.
Q. Do engineers in your field do animal testing?
A. Not in my field. Not in the area of mechanical engineering that I specialize in.
Q. And if you believed any other testing was necessary to confirm opinions, would you have asked for it?
A. Yes, I would have.
Q. And did you?
A. I found no reason to ask for further tests or calculations.
Q. Now, in terms of Bard documents, have you disclosed everything that you have reviewed in your opinions?
A. Yes, I have.
Q. And are you aware that that information was given to Bard and its lawyers?
A. I'm aware of that, yes.
Q. And before today, have the Bard lawyers talked to you, taken your deposition?
A. Yes, they have.
Q. And during that deposition, has a Bard lawyer ever showed you a document and asked you to consider it --
THE COURT: Mr. O'Connor, we need you to stay at the

mic, please.
BY MR. O'CONNOR:
Q. -- and asked you to consider that document to see if it would change your opinions?
A. Not to my recollection, no.
Q. Has a Bard lawyer ever told you that they had documents, they had tests that would refute the findings and conclusions that you made?
A. The only one where that was the case is the 400 million cycle test of the Recovery. But other than that, I -- that situation never arose in my interactions with the Bard lawyers.
Q. Have you ever seen a 400 million -- what did you say, recycle test?
A. 400 million breathing fatigue test on the Recovery. I've never seen the lab notebook or a report on that test.
Q. And certainly if there was a document that Bard had that would show that the ones you looked at may not be accurate, you certainly would have -- would you have expected them to show it to you?
A. I would have, yes.
Q. Are you comfortable that you have reviewed everything you needed to review, everything that was available, to come in here and give the opinions you've given to the members of this jury?
A. I am.

Q. And if you needed anything else, would you have advised us?
A. I would have asked for it, and I would have expected to receive it.
Q. And, again, are your opinions here today to a reasonable degree of scientific and engineering probability?
A. Yes, they are.

MR. O'CONNOR: Thank you.

THE COURT: All right. Thank you, Dr. McMeeking. You can step down.

(Witness excused.)

MR. LOPEZ: Your Honor, at this time the plaintiffs are going to call Dr. Rebecca Betensky.

THE COURTROOM DEPUTY: Ma'am, if you'll stand right here and raise your right hand.

(The witness was sworn.)

THE COURTROOM DEPUTY: Could you please state and spell your name for the record, ma'am.

THE WITNESS: Rebecca Betensky. R-E-B-E-C-C-A, B-E-T-E-N-S-K-Y.

THE COURTROOM DEPUTY: Thank you, ma'am. Please come have a seat.

MR. MANKOFF: May I proceed?

REBECCA BETENSKY, PH.D.

called as a witness herein by the plaintiffs, having been first duly sworn or affirmed, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. MANKOFF:

Q. Good afternoon, Dr. Betensky. Could you please introduce yourself to the jury.

A. Yes. Good afternoon. I'm Rebecca Betensky.

Q. And what is your field of expertise?

A. I'm a statistician.

Q. And do you also study in the area of biostatistics?

A. Yes. So I'm in a department of biostatistics, meaning that the applied work that I do and the methods that I develop are motivated by problems in medicine and science.

Q. And in your field, do you also use epidemiology?

A. Yeah, I do.

Q. And can you explain what epidemiology is?

A. So epidemiology encompass -- is primarily focused on understanding risks of disease, for example, or risks of certain kinds of events. It also includes a large methodological component, so there are methods developed within epidemiology.

Epidemiology is often what's needed and used for data that come from observational studies, so studies that are not nice engineering-type experiments or nice clinical trial experiments, but purely observational data require certain kinds of methods, and those fall within the category of epidemiologic methods. But there's a very large intersection

with statistics.
Q. And where did you get your undergraduate degree?
A. Harvard College.
Q. And what was your degree in?
A. Mathematics.
Q. And your doctoral degree, where did you get that degree?
A. Stanford.
Q. And is there one degree or are there multiple degrees?
A. Just one Ph.D. in statistics.
Q. And do you currently have an academic appointment?
A. I do. I am professor of biostatistics at the Harvard T.H. Chan School of Public Health. And then I also have an appointment as biostatistician at Massachusetts General Hospital.
Q. And do you teach in this field?
A. I do.
Q. What level of student?
A. Graduate students, so just graduate students, although I have advised undergraduates. But my courses are graduate courses.
Q. And how long have you been doing research in biostatistics and epidemiology?
A. 25 years.
Q. Do you do original research on statistical techniques?
A. I do.

Q. And do you do research involving studies -- do you collaborate with doctors in doing research as well?
A. Yes.
Q. And I understand that you are starting a new appointment soon?
A. I am.
Q. Okay. Can you explain what that is?
A. Sure. So as of October 1st, I'm leaving my positions at Harvard and Mass General, and I am beginning a position as chair of the biostatistics department at New York University, NYU.
Q. And what -- can you explain more about that department? How big is that department?
A. So it's a new department that's -- the School of Public Health, which they call the College of Global Public Health at NYU, is about three years old, and I'll be the inaugural chair of the department. So currently there are three faculty members in the department, and I have arranged to be able to hire several more over the next several years.

And there currently are, I believe -- this may not be exactly correct -- but I believe about 30 master students and about 400 undergraduates who concentrate in public health. And one thing I'll be doing there is starting a Ph.D. program as well.

Q. Have you published peer-reviewed articles involving these

fields, biostatistics?
A. Yes.
Q. And have you published peer-reviewed articles involving collaborative research with doctors?
A. Yes.
Q. Have you consulted with companies, pharmaceutical or medical device companies?
A. Yes, I have.
Q. Can you explain a little bit more about that?
A. Yes. So I currently serve on maybe five to seven data safety monitoring boards. Sometimes they're called data monitoring committees, so DMCs or DSMBs, for pharmaceutical companies for the purpose of monitoring the safety of clinical trials.

So I, as the statistician member of the committee, sit with physicians and sometimes patient advocates and others and review safety data, sometimes efficacy data as well, but mainly safety data from the trials and look very carefully at the risks that patients are incurring on these trials and make decisions as to whether the trials should continue or should be stopped due to safety concerns.

Q. Are you being paid for your time testifying here today?
A. Yes, I am.
Q. Are you charging an hourly rate?
A. I am.

Q. What is the rate?
A. $850 an hour.
Q. And approximately how many hours will you be charging for?
A. Well, as long -- however long I testify for. And then other time, I charge $700 an hour for litigation consulting time, which regarding this trial may be -- may be 10 to 15 to 20 hours. I'm not sure.
Q. Okay. And is your research that you were describing earlier supported by grants?
A. Yes. Yes, grants from the National Institutes of Health, mainly, or I think entirely.
Q. Okay. And can you estimate the total amount of grant money you've brought in, say, in the last five years?
A. So the last five years would be approximately over a million dollars.
Q. Okay. So turning to your opinions in this case, you were asked to provide three separate analyses; right?
A. That's correct.
Q. Okay. So just -- can you just give a brief overview? You looked at Bard's failure predictions. Can you just describe briefly what that analysis involved?
A. So I was provided with documents that Bard compiled at the launch of new products in which they considered all the different various failure -- failures that could occur within patients and made predictions as to the likelihood of those

occurrences, is what they call them. And so I did an analysis comparing different products looking at Bard's own assessment of likelihood of these occurrences.

Q. And what was your overall conclusion based on that analysis?

A. So based on that analysis, in comparing various products with the Simon Nitinol filter product, most uniformly, the later Bard products had higher or equal likelihoods of failure as compared to the SNF, the Simon Nitinol filter.

Q. And we'll go into that in more detail in a minute.

Now, your second analysis involved failure reports; correct?

A. That's correct.

Q. And can you, again, give an overview of what you looked at there?

A. So for that analysis, again, I used data that was provided by Bard that included detailed counts of failures, the various different types of failures that are relevant and of interest for these filters. So Bard provided the counts of these failures as well as the sales data, so the numbers of these filters presumably that went into patients.

And so using those -- those data, I was able to make comparisons between products as to the risks of those events over different time periods.

Q. And what was your overall conclusion in that analysis?

A. So, again, in that analysis it appears that the Bard products, beginning with the Recovery filter and moving later in time, are associated with higher risks of the different failure types as compared to the SNF. And in some cases much, much higher; in some cases higher. And in a few cases, it was -- because of some sparse data, it might be indeterminate.
Q. And your third analysis involved looking at Bard's bench test data; correct?
A. That's correct.
Q. Okay. And again, can you give an overview of that analysis?
A. Yes. So I was provided with data from an experiment, from a bench test experiment, looking at an outcome of resistance. And the comparison was between the SNF filter and the Recovery filter, and it was looking at two different temperatures and comparing those two devices with respect to resistance. And so I analyzed that data to investigate whether there was a difference in this resistance measure between devices.
Q. So let's look now in detail at the analysis involving Bard's failure predictions.

You looked at documents titled Design Failure Mode Effects Analysis. Can you explain what that means, what those are?
A. Yes. So those are -- those are complicated tables that include the different failure modes and then several

subcategories of those and -- of those failure types and then an assessment by Bard, which is -- was a score that they assigned either from 1 to 10 or 1 to 5, which was associated with the likelihood of the occurrence of the health effect of that failure.

Q. So it's a prediction of how often a particular failure would occur?

A. Of the likelihood of that failure.

Q. And how many of these separate documents did you review?

A. Several. There are many of them, many -- many, many pages of them.

Q. Okay. So let's look at one briefly.

MR. MANKOFF: Can you pull up trial Exhibit 1763?

BY MR. MANKOFF:

Q. Is this one of those documents you're describing?

A. Yes, it is, but is it possible to make it a little bigger?

Q. We'll zoom in on the relevant area.

A. Okay.

MR. MANKOFF: But first I'd like to move for admission of trial Exhibit 1763.

MS. HELM: I'm sorry, Your Honor. I'm having a hard time.

MR. MANKOFF: Can you zoom in on the header?

MS. HELM: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit No. 1763 admitted into evidence.)

MR. MANKOFF: May we display it to the jury?

THE COURT: Yes.

MR. MANKOFF: And if you could zoom in on the top text in the header, please.

BY MR. MANKOFF:

Q. And so does this document relate to the Simon Nitinol filter?

A. Yes, it does.

Q. Okay. And what time period is this document relevant to?

A. So that is in the comments field, and it's look -- it's relevant to January 2004 through December 2006.

Q. Okay. And if we could go to page 5, please.

And is this showing a category of a particular potential failure?

A. Yes.

Q. So, for example, number 5 is deployment?

A. Yes.

Q. And what provides the prediction of the occurrence?

A. So I guess it's a little bit hard to see that from this blown-up view, but back on the original view, there is a column a little bit to the right of the middle that's labeled O. And that refers to occurrence.

And within that column is a number, in this case it would include -- could potentially include 1 -- the numbers 1

through 10. On this page we only see 1 through -- maybe we only see 2 through 6. And that's a code for an associated range of probabilities of -- meaning the likelihood of the event.

Q. Okay. And let's go to page 18, please.

And under 2, does this involve Bard's predictions about the likelihood of migration for the SNF filter?

A. Yes, it does, or at least for the categories shown on this page.

Q. And page 21, please.

And under 3.2, does this show Bard's prediction for a particular occurrence of fracture with the SNF filter?

A. Yes, it does.

MR. MANKOFF: Okay. Can we pull up trial Exhibit 631, please.

BY MR. MANKOFF:

Q. Is this another document providing Bard's failure predictions for the G2 Express?

A. Yes. I see that labeled on the top.

MR. MANKOFF: Can you blow that up, please?

And I would move for admission of Exhibit 631.

MS. HELM: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit No. 631 admitted into evidence.)

BY MR. MANKOFF:

Q. Now, it's hard to read, but on the upper right-hand corner there's an identifier number. I believe it's 7044. And we'll see that correspond later, so I wanted to point that out.

Can you tell us what time period is relevant for this document?

A. Yes. June 2005 through February 2007.

MR. MANKOFF: And can we go to page 16, please?

May we publish, please?

THE COURT: Which one?

MR. MANKOFF: Trial Exhibit 631.

THE COURT: The page you're going to or the page you just left?

MR. MANKOFF: The page I'm going to.

THE COURT: Yes.

BY MR. MANKOFF:

Q. And is this -- does this show Bard's predictions for deployment issues similar to what we saw with the SNF?

A. Yes. I do think it says deployment there, yes.

Q. Okay. And we're going to turn to a better copy of this in a minute.

Can we go to page 20, please.

And under 2 at the bottom, does this show Bard's prediction -- at least one of Bard's predictions for migration for the G2 Express?

A. Yes. I can't read that word all the way on the left next to 2, but I see it says migration is the second word.
Q. And I don't know if you can read it, but is the 2.1, is that category different from what we saw with the SNF?
A. Yeah. So 2.1 is -- and I may be mispronouncing this -- cephalad migration. So it's a subcategory of migration which Bard has introduced in these documents with the G2 Express that was not used, they did not use in their SNF version of these documents.
Q. Can we go to page 26, please.
And does this show another type of migration prediction? If you can zoom in on the 2.8.
A. Yeah. So this is showing what's called caudal migration, which is downward migration, so again, a different subcategory of migration. And, again, what -- something that wasn't provided or used in the SNF version of these documents.
Q. Can we pull up trial Exhibit 635, please.
And is this the same document relative to the Eclipse?
A. Yes.
MR. MANKOFF: I move for admission of trial Exhibit 635.
MS. HELM: May we see it enlarged, please?
No objection, Your Honor.
THE COURT: Admitted.
(Exhibit No. 635 admitted into evidence.)

MR. MANKOFF: May we publish?

THE COURT: Yes.

BY MR. MANKOFF:

Q. And in the upper right-hand corner, the identifier number ends in 7077.

But can you tell us what time period this document is relevant for?

A. June 2005 through March 2009.

Q. And did you use this document in your analysis?

A. Yes, I did.

Q. And does it follow a similar format to the other two we looked at?

A. Yes.

Q. Did you see any testimony from Bard employees about how these documents are used by Bard?

A. Yes, I did.

Q. Okay. And what did you learn?

A. Yeah, so -- so I know that the vice president of quality, Mr. Chad Modra, testified regarding these documents. And he said that the occurrence rating is an important part of Bard's risk assessment. And in support of that, Bard has a standard operating procedure document, an SOP, related to this which uses the occurrence ratings from their evaluation process.

And he also -- this is from my report. He also testified that prior to launch --

MS. HELM: Objection.

THE COURT: Hold on.

MS. HELM: Objection, Your Honor. It's hearsay. She's reading from her report.

THE COURT: Well, the testimony is from your memory, Doctor. If you need to have it refreshed, you can tell the questioner. But you need to testify not from your report but from your memory.

THE WITNESS: Okay. That, according to my memory, he testified additionally that these ratings were important at launch for the company to evaluate the new product with regard to its risks and potentially to make adjustments, if necessary, and to know what they were.

MR. MANKOFF: Can we pull up trial Exhibit 641, please.

Your Honor, I move to publish -- I'm sorry.

BY MR. MANKOFF:

Q. Can you describe what this document is, please?

A. Yes. So this is a distillation of the previous documents that we looked at into a format that allowed me to compare, as best as possible between filters, comparable categories. And so this extracted -- so in this document, the different categories are extracted and lined up to make for apples to apples kind of comparison.

Q. And will this help you to explain your opinions to the

jury?
A. Yes.
MR. MANKOFF: Your Honor, I move to publish trial Exhibit 641 as a demonstrative.
MS. HELM: Your Honor, I have an objection. And may we approach at sidebar?
THE COURT: Yes.
If you want to stand up, ladies and gentlemen, feel free.
(At sidebar on the record.)
THE COURT: I think I'm going to give each side about six beans or chits, and you can use them for sidebars.
MS. HELM: All right.
THE COURT: That's okay. We've had a lot of sidebars in our first two days.
MS. HELM: I'm feeling appropriately chastised, Your Honor.
That exhibit and the column should be redacted. It has a column for Recovery death. And pursuant to our prior agreements and your prior rulings, I couldn't see -- I'm looking at it on the screen, but I'm able to see Recovery deaths, so he can't publish that.
THE COURT: Is there a Recovery death column?
MR. MANKOFF: I was not aware of a Recovery death column, but can I -- is this on the first page?

MS. HELM: No. It's on the page that you're getting ready to publish.

MR. MANKOFF: On that first page?

MR. ROGERS: Whatever page is up on the screen.

MS. HELM: Whatever page is on the screen.

MR. MANKOFF: I will switch pages before I publish, and I will not show any page involving Recovery death.

MS. HELM: You'll agree that the exhibit before it's admitted will be redacted?

THE COURT: So it's not going to be admitted. It's a demonstrative.

MS. HELM: He moved to admit the document.

THE COURT: He moved to publish, not to admit.

MS. HELM: It needs to be --

THE COURT: Well, so you're not going to use the page with Recovery deaths?

MR. MANKOFF: I'm not. But I would also point out that this is just a prediction. It doesn't say what happened.

THE COURT: Well, I haven't seen it so I -- but it sounds like you don't need that for what you're about to do.

MR. MANKOFF: Yeah.

THE COURT: Why don't we go ahead and publish it without that. If you think at some point it's needed, then we can talk again about whether it's appropriate.

MR. MANKOFF: Okay.

THE COURT: Okay.

MS. HELM: And, Your Honor, I didn't feel like I could address that from counsel table.

THE COURT: I understand. I'm still going to hand out beans.

(End of discussion at sidebar.)

THE COURT: Thank you all.

All right. Counsel, you can publish the page we discussed.

MR. MANKOFF: Well, can we switch to page 5, please.

And I would move to publish this page as a demonstrative.

THE COURT: Any objection?

MS. HELM: We have three sets of very old eyes looking at this, Your Honor.

THE COURT: That's evident to the rest of us in the courtroom.

MS. HELM: No objection, Your Honor.

THE COURT: All right. You may publish.

MR. MANKOFF: Can we blow that up, please?

MR. LOPEZ: You want just the first -- like the top first or the whole thing?

MR. MANKOFF: The first half, top half.

BY MR. MANKOFF:

Q. Can you describe what we're looking at here?

A. Yes. So here we're looking at comparison of SNF on the left and G2 Express in the middle and the right. And again, as I mentioned, this is sort of a summary and a distillation of what we had seen on those Bard documents just previously.

So in particular here, the failure mode is migration. And so for SNF, it's just migration because that was the category that was used in the SNF document. And potential causes of failure there are listed, such as twisted legs, tilted filter, et cetera, going down that third column from the left.

And then there is an occurrence rating, which we saw on the previous Bard table, that O column that I pointed out. And then the next column over titled "Probability Range" is just the translation of that code.

So a 2 for occurrence means a range of probability between 1 over 150,000 to 1 over 20,000. And so that was the assessment of Bard as to the cause -- as to the cause of failure, that particular cause of failure associated with migration.

Q. And so -- and what's the category being compared for the G2 Express?

A. So for G2, it's -- the overall migration from SNF is, in this case, compared to the cephalad migration, because as I mentioned previously, the G2 document from Bard separated out migration into the two categories of different types of

migration and didn't consider a single category of migration.

So here I've listed the cephalad migration category.

Q. And the probability ranges are the same?

A. In this case, they are the same, in what we're looking at on this screen, yes.

Q. And I should tell you that if you want to emphasize a particular area, you can draw on it. You can circle on the screen. That may help.

A. With what?

Q. With your finger.

THE COURT: With your finger.

THE WITNESS: Okay. Great, thank you.

MR. MANKOFF: Can we go to the next page, page 6? And zoom in on the top half again, please.

And may we publish this to the jury as a demonstrative?

THE COURT: Yes.

BY MR. MANKOFF:

Q. And so here we're looking at -- can you explain what we're looking at here?

A. Yes. So it's the same -- same idea as what we just looked at. So, in fact, it's exactly the same for SNF. So here it -- I just repeated the migration failure mode from what was previously shown on the previous page. But for G2 Express now, I have listed the other migration subcategory because, again,

the G2 Express document from Bard broke it down into the two categories of migration. This one is called the caudal or downward migration category.

Q. So is Bard predicting that each type of migration for the G2X will happen as often as the one type for SNF?

MS. HELM: Object to form, Your Honor. It's leading.

THE COURT: Sustained.

BY MR. MANKOFF:

Q. What is Bard's projection for each category for the G2 Express compared to the one category in the SNF?

A. So on this document, on this page, just like on the previous page for the cephalad migration, the probability ranges are the same for the G2 Express as they are for the SNF. However, we need to remember that -- or in evaluating this, we need to take into account that the SNF migration includes both categories that the G2 Express is listing separately.

So in order to really make the comparison between G2 Express and SNF, we would have to add the probabilities between the two sheets. So the caudal plus the cephalad could better be compared to the overall migration on the SNF.

Q. I'd like to look at the same information for the Eclipse.

MR. MANKOFF: Can we go to page 9, please. And can you zoom in on the same area?

I move to publish this to the jury.

THE COURT: You may.

BY MR. MANKOFF:

Q. Is this the same comparison except SNF with Eclipse?

A. I'm sorry, can you repeat that?

Q. Yeah. Is this the same comparison as we looked at for the G2X only now we have the Eclipse?

A. So this is the comparison of the cephalad migration for Eclipse to the overall migration for SNF, yes.

Q. And can we go to page --

And, sorry, and the probability ranges are the same for each filter; correct?

A. They are. However, I'm noticing that the subcategories on Eclipse seem a little -- are a little different at the bottom. So whereas SNF combined wire fracture and detachment, here it looks like Eclipse may have further separated out -- although maybe if we could see a little bit lower in the document.

Q. Can you indicate where you're looking?

A. Yeah. I'm sorry.

Okay. Right. So these two circles are what I'm comparing, and I'm just noticing that SNF -- the SNF document combined the wire fracture and detachment category, whereas the Eclipse broke those out into two subcategories within their subcategory of cephalad migration. So now they have a sub-subcategory or they've introduced sub-subcategories of migration.

Q. And do they make separate predictions for each of those?

A. Yes.

MR. MANKOFF: Can we go to page 10, please?

May we publish?

THE COURT: Yes.

MR. MANKOFF: Can we zoom in on the same area?

BY MR. MANKOFF:

Q. And what are you comparing here?

A. So here it's the caudal migration for Eclipse compared to overall migration for SNF.

MR. MANKOFF: And if we can back up to page 8, please.

Can you highlight the bottom half -- or zoom in on the bottom half.

And I move to publish.

THE COURT: You may.

BY MR. MANKOFF:

Q. Can you explain what's being compared here?

A. So here we have fracture being compared between the SNF and the G2.

Q. And what was Bard's prediction for fracture for the SNF?

A. So for the SNF on the left, the prediction for user error is the range 1 over 150,000 to 1 over 20,000. So that's this top circle.

And the range for material fatigue due to movement is 1 over 20,000 to 1 over 10,000. And that's the bottom.

Q. And what was Bard's prediction for the G2 Express?

A. So let's see. So if I compare the second category, the material fatigue due to movement, and then it's further qualified against osteophyte of a vertebra of IVC wide branch vessel, compare -- so that seems like a -- to be a subcategory of -- circling too many things, but subcategory of what the SNF had, which was just material fatigue due to movement and didn't further qualify it.

So the prediction by Bard of that occurrence is what I have underlined here for G2, 1 over 10,000 to 1 over 5,000. So it's a smaller category but has actually a larger and, in fact, twice the likelihood predicted as over in the SNF for the larger category of material fatigue due to movement, which is 1 over 20,000 to 1 over 10,000. So twice as likely for SNF as for G2 Express.

Q. Do you know what movement against osteophyte of a vertebra is?

A. I know that osteophyte is bone-related.

Q. Fair enough.

And did Bard make other predictions on this page about G2 Express fractures?

A. Yes. So there are other -- other -- these other categories are all related to fractures for G2, so these different categories that are all listed here. So going from the bottom, snare tip -- I can't -- I can't -- weld joint to bundle fractures. Anyway, biomechanical forces here, filter delivery

issues, caudal movement.
Q. Sorry to interrupt. Can you indicate what you're reading?
A. Yeah. I'm sorry. So I'm looking in this column here, and I'm just reading up the different kinds of failure -- failures related to fracture listed here for the G2.
And their probability -- their associated probabilities, except for this last category, which is this one here, so except for this one, they're all 1 over 10,000 to 1 over 5,000, which is much larger than the predicted probability for the SNF in the first case, so that's this one, which is 1 over 150,000 to 1 over 20,000; and twice the likelihood as for the second category, the 1 over 10 -- sorry, 1 over 20,000 to 1 over 10,000.
Q. And so are you able to make a comparison of the total expected fractures or predicted for the SNF versus the G2 Express?
A. So -- so what we could do -- so I can make a couple of comparisons. So one comparison would be that the G2 predict -- the prediction of these fracture events for G2 Express are equal to or -- sorry, let me take that back -- are less than those predicted for SNF in all cases except for this last case, which is equal to -- I'm sorry. I think I misstated that. Let me completely back that up.
So the predictions for the G2 fracture events are larger than those predicted for the SNF, except for this one

down here that I circled and now pointed to, which is comparable to one of the SNF predictions. So that's one comment I can make.

The other comment would be that if I tried to -- if I tried to combine across all events to try to get a single probability for a fracture event for SNF and a single probability of a fracture event for G2 Express, it would be larger for the G2 Express. In other words, if I just added up these probabilities for the G2 Express and compared them, that single number to the sum of the probabilities for the SNF, it would be larger.

Q. And are these predictions for the likelihood of a fracture, or what exactly is being predicted here?

A. So these predictions are for the --

MS. HELM: Your Honor, I have to object. She's interpreting the document, and she's not here as an engineer or an expert on DFMEA.

THE COURT: Overruled.

THE WITNESS: Can you repeat your question, please?

BY MR. MANKOFF:

Q. So are the -- what is Bard predicting specific to fractures here?

A. So the prediction is for the health event, the health effect of the fracture. And so it's the end result of a fracture, and then the fracture leading to a complication, and

then that complication leading to the ultimate critical health effect.

Q. And if I could direct your attention to the second column for the G2 Express, what is the health hazard that is being evaluated here?

A. So as it says in this category here, critical, it's called -- it's designated as a critical health hazard, which can contribute indirectly to a death, severe injury, permanent significant disability, or severe occupational illness in a patient.

Q. Now, just stepping back for a minute, did you make an overall assessment of what Bard's prediction was for the G2X filter related to fracture?

A. I didn't --

Q. I believe you had that in your report. I can pull that up if you need to refresh your recollection.

A. Okay. Sure.

MR. MANKOFF: Can we have -- I'm sorry. I don't have the exhibit number, so I will move on.

Is she able to refresh her recollection with her report in front of her?

THE COURT: Yeah, if you identify the document. Do you have an exhibit number?

MR. MANKOFF: I don't have the exhibit number.

THE COURT: We need to identify it by exhibit number.

BY MR. MANKOFF:

Q. Well, let's move on to your analysis of Bard's failure reports.

What data did you use to analyze those reports or to gather the information necessary?

A. So I used data provided by Bard that, as I explained before, included the counts, the numbers of these adverse events or failures by failure type, by filter, and by year, along with sales data that they provided for their filters within the same time periods.

Q. Can we see trial Exhibit 665, please.

Did you prepare this to help explain your opinions to the jury?

A. Yes, I did.

MR. MANKOFF: May we publish as a demonstrative?

THE COURT: Any objection?

MS. HELM: Not as a demonstrative, Your Honor.

THE COURT: You may publish.

MR. MANKOFF: Can we zoom in to the first six rows in the first block?

BY MR. MANKOFF:

Q. Can you explain what we're looking at, please?

A. Yes. So first of all, starting all the way on the left, July 2010 means that I included here data that was provided by Bard through July 2010.

And then in the next column, which I'm underlining right now, I've listed the comparisons that I'm making between the various filters. And then what's in the table are what's called reporting risk ratios. So let me explain that.

So I'll start with risk. So by "risk," I mean simply the number of events of a given type. So, for example, if we're talking about migration, such as in this first column, the risk would be the number of migration events through July 2010 divided by the number of sales of -- of a particular filter through 2010. So that would be the risk of migration.

But that's not what I'm showing you here. I'm showing you a risk ratio. So what I've calculated is the ratio of two risks. So that's just, again, simply, the risk of migration through July 2010 in this case -- in this first case for Recovery, divided by the risk of migration through July 2010 for SNF. So that's what I mean by "risk ratio."

And then finally, I've used the qualifier "reporting" to indicate that these are based on reports or various other ways that Bard collected their data on these events. And so I've listed them -- again, so risk ratio is a comparative measure, and so that's what this table is. It's about comparing pairs of filters; and then furthermore, I did it separately by category of failure type.

Q. Okay. And by way of example, if we can focus in on the G2X filter fracture number, can you boil it down and explain what

information we have from that?
A. So if you -- do you mean filter fracture plus?
Q. Yes.
A. Okay. So that would be this column here all the way over on the right. And so the G2X as compared to SNF has a reporting risk ratio of 4.29. And so what that means is that the risk of filter fracture plus, which includes another category which later showed up in Bard's data that they provided, so the risk of that filter fracture event for G2X is estimated to be 4.29 times the risk of filter fracture for the SNF filter.
Q. So does that mean that relative to the sales for the two filters, the fractures are being reported more often with the G2X?
MS. HELM: Object to the form, Your Honor. It's leading.
THE COURT: Sustained.
BY MR. MANKOFF:
Q. If we could look at the Eclipse row, the filter fracture column as well, can you explain the .47?
A. Yeah. So that .47 is -- has the same -- it's a different number, obviously, but has the same interpretation. And so what that means is based on the data, meaning based on the numbers of filter fracture plus events, the risk of that event for a patient receiving the Eclipse is .47 times the risk of

that event for a patient receiving an SNF filter based on data through July 2010.

Q. Does that mean that there were fewer fractures occurring with the Eclipse? Are you able to make a comparison?

MS. HELM: Object to the form, Your Honor. He's leading.

THE COURT: Overruled.

THE WITNESS: So that means that that's the estimate based on the data, but the estimate alone is not all that informative as it is -- or similarly to every other number within this table. So what has to accompany any estimate is some measure of precision of that estimate, how close to the unknown is it.

And so -- so we would want to know that for that number, that .47, and for every other number in the table. As a statistician, or anyone analyzing data or anyone analyzing a study needs to go beyond the estimate and look at the information contained within that estimate, and we don't get that from this table alone.

BY MR. MANKOFF:

Q. So are you saying that you evaluate whether the statistic is meaningful or whether the differences are meaningful?

A. Right. So that's what would need -- that's what does need to accompany these estimates.

Q. Okay. And what was your conclusion with respect to the

Eclipse?

A. So I think -- I need -- is it possible to maybe enlarge this part of the table, please?

MR. LOPEZ: I think we have to erase it first, don't we, Judge?

THE WITNESS: Okay.

Okay. So, let's see. So what I've listed here are what's called p-values. And so the p-value is a measure of evidence, and it's used all the time in any kind of statistical analysis, whether it's an experiment of machines or animals or people or anything.

And so this gives us a measure of how -- of how different the observed estimate is relative to some benchmark. And in this case, the benchmark is a risk ratio of 1, because a risk ratio of 1 would mean that the two filters that are being compared are the same with respect to risk. If you divide one risk by the other and it's 1, then that would mean that there's no difference between the risks of those two filters.

And so what I've done here is I've conducted a statistical test based on Bard's data that were provided to me to assess how -- what's the likelihood that -- or how certain can I be to reject that benchmark of 1 given the observed data that I have.

And so the way that this works is that a very small p-value, which is a probability, gives me strong evidence that

the estimate did not arise by chance alone but did arise because that true underlying risk ratio in this case is different from 1.

And so that's a long-winded answer, but if we look at these p-values in the top part of the table, so that's these -- this part of the table, and these are associated with that original top part of the table that we were looking at, the July 2010 data, and you can see the comparisons there.

And so what we can see -- we were talking about the comparison of SNF -- sorry, of Eclipse versus SNF. The estimate, remember, was .47. So that's what was here. And on this portion of the table, I've listed the p-value associated with that, in other words, with testing whether that .47 is significantly different from 1, our benchmark.

And so I get a large p-value, .7168, et cetera. And so I conclude from that that there's no evidence that it's less than 1; there's no evidence that it's greater than 1. And that's -- and that's what I take away from this Eclipse versus SNF comparison.

BY MR. MANKOFF:

Q. So to try and boil it down a little bit, is there evidence that there is -- is there enough evidence to draw a conclusion about this particular comparison?

A. Based on the p-value, there isn't.

I would additionally look at what's called the

confidence interval, which I also calculated. And I don't know if we can pull that up or if I can just tell you what it --

Q. You can -- if you remember --

A. It was -- it's on this same document, just a subsequent tab.

Q. Do you remember what you wanted to say about the confidence interval?

A. Yeah. So the confidence interval for this comparison -- so, remember, the estimate was .47. The confidence interval -- and I'll explain in a second what that is, but the confidence interval was something like .05 to 5. I'm certainly not right about that, but that's more or less the gist of it, or maybe it was .05 to 3. The point is is that it's wide and it contains that benchmark value of 1.

Now, a confidence interval is an interval that gives us 95 percent confidence, in this case, that that true ratio is contained within it. And so if we have a very wide confidence interval, including that benchmark value of 1, we really don't have any information at all.

MR. MANKOFF: Can we go to page 12, please.

BY MR. MANKOFF:

Q. How many events were evaluated --

Let me just back up and ask what -- generally, what are we looking at here on this page?

A. So I --

Q. Is this the underlying data for what we were looking at before?
A. Yes. So this is the data through July 2010, the underlying data that went into those calculations that were on that summary sheet, yes.
Q. So what -- on the far right-hand column, filter fracture plus detached component, how many of those occurred with the Eclipse?
A. One. So that's -- that's right here.
Q. And what does that tell you about the estimate we were looking at?
A. So that's a small number; and in addition to that, the sales number is small, relatively small. And so that's really what's driving that confidence interval and that p-value. In other words, we don't have enough information to be able to make a strong definitive conclusion or to make an inference from that data. The error in that estimate is too large due to the small numbers.
Q. And were you able to gather additional data about Eclipse fractures?
A. Yes. I was -- I later was provided with or was able to access and was provided data through a later time point in 2010 and also through 2011. And with more data, this began to stabilize.
And the Eclipse versus SNF reporting risk ratio was --

I forget the number, but maybe something like 3.5. And it was statistically significant, meaning a small p-value. Very small p-value, yeah.

Q. And is the -- can you describe, then, what your overall conclusion is about your analysis of the failure reports compared to the SNF?

A. Yes. So based on, you know, what we saw in the summary page and all of the -- and all of the analyses that I did, it's very consistently seen that the Recovery filter and then subsequent filters, including the G2, G2X, Eclipse, all have higher reporting risk ratios than the SNF. And in some cases, they're considerably higher; and in later cases, they're higher.

Q. Now, as we just saw, as you have more data, you can be more precise; but we never have perfect data. Did you do anything to account for the imperfect information you were working with here?

A. Yes. I did a couple of what we call sensitivity analyses, which means I tried different ways of analyzing the data or tried tweaking the numbers, not because that's what I believe as the truth but just to see what would happen.

Q. And so did you do a sensitivity analysis involving the reports for SNF?

A. Yes, I did. So one analysis that I did was to add five events to each category for the SNF filter. And then I reran

my analysis. So that -- that would be penalizing the SNF by giving it more events, but given that there were a small number of events, I wanted to see how sensitive the results were to having a very -- you know, having zeros or having very small numbers. So I added five just to see what would happen.

Q. Is this type of analysis that we just went over involving the reported failures, is that something that you've seen in the peer-reviewed literature?

A. Which type of analysis are you talking about?

Q. This comparison that you've been describing to us involving the failure reports.

A. So this is a -- this would be a common kind of analysis. I'm aware of a couple published papers that have similarly looked at events and tried to estimate event rates or event proportions and -- or risks and have compared them.

Q. Okay. Let's talk about potential limitations. Can you explain what that means?

A. Yeah. So -- so any data analysis has potential limitations. That's just the nature of experimentation, whether it's a designed experiment or an observational study. So there will be limitations.

And we don't know if those are -- if -- so we can identify potential limitations, so in other words, factors that if they were true, if they held true, could influence or affect the interpretation of the results. We often don't know if

those factors are true or not, but it's still important as a scientist, any -- you know, for any scientist to consider what could possibly be wrong or what could possibly be a limitation.

And so that's one aspect of what I thought about with regard to this analysis.

Q. And what potential limitations did you consider? Let's go through them one by one.

A. Okay.

So one limitation -- one potential limitation is that the sales numbers don't exactly reflect the numbers of people who were implanted with these filters. So just because Bard sells a certain number of filters to a hospital doesn't mean they use them all. Maybe they sit on the shelf. Maybe they get returned.

And so I ran one sensitivity analysis where I discounted the number of sales. So -- and I discounted it by 20 percent, just as a number that I chose that seemed not too big, not too small, but perhaps reasonable given that any buyer wouldn't want to -- wouldn't want to overpurchase.

And the reason for doing that would be not that it would change the risk ratio, because it wouldn't given that we're talking about a ratio discounting by the same amount falls out of the estimate, but it could have an effect on the precision of the estimate. Again, as we saw when we were talking about Eclipse, the numbers of events matter and the

numbers of sales matter.

And my finding -- my findings were the same. And certainly the numbers changed, the p-values changed, the confidence intervals changed a little bit, but the overall findings were the same with regard to that consideration.

Q. Okay. Any other potential limitations that you considered?

A. Yeah. So -- let's see. What else did I consider?

So another consideration in an analysis like this could be what's called confounding or channelling of patients. So one very big serious concern in any kind of observational study is that since it's not randomized, so patients are not randomly given SNF versus G2X, there may be some reason why a patient receives one versus the other.

And that would be important to potentially consider, because if -- but only if whatever that factor is that determines which filter they get is also associated with their likelihood of the failure event.

So if it's -- if their characteristic as a patient is only associated with one of those, let's say, you know, I'm making -- if they have blonde hair, they're more likely to get the SNF, but having blonde hair has no impact at all on migration, then that doesn't matter. It doesn't matter at all if there's an imbalance in blonde hair.

Where it would matter is if that feature were related both to the failure event as well as to the selection into the

filter. Unfortunately, I couldn't do any analysis that took account of that because I didn't have the data. Bard did not provide that data. I don't have patient-level data that was provided that I could use.

Q. But on the bottom line, did you estimate that that would change your conclusions?

A. So that -- that -- I'm not aware of any such feature, and typically that may make a small -- you know, could have a small impact.

My overall sense is that given that these estimated risk ratios in many cases are very, very large, it might change them and reduce them somewhat but probably wouldn't make them go to 1. That's my sense from looking at the numbers and the magnitudes of the numbers and their consistency across events within filters or within comparisons.

Q. Now, did you find data or counting errors when you were reviewing the underlying spreadsheets that Bard provided to do your analysis?

A. Yes, I did. So when I began this analysis of the adverse event, the failure estimation, and I went to the original Bard spreadsheets, they're complicated spreadsheets. And for those of you who work in Excel, you know how easy it is to make mistakes within Excel, and especially if you're using formulas between sheets.

And so the way that these sheets were structured is

that the first page was a summary page of numbers of events, so numbers of migrations, numbers of fractures, that kind of thing. And then subsequent tabs on this worksheet, this workbook, included the raw data.

And there were formulas that were used to count the individual rows, which were events from each -- you know, from individual patients. So there were formulas, because nobody would want to go through thousands of rows or however many there were, so formulas were used to count the numbers of events using text fields. And there were some mistakes that were made that I discovered when I clicked on the cells and looked more carefully.

So in one case there was just an error there that amount -- that led to zero migration events. I think it was for the Recovery filter, although I don't remember exactly which filter it was for -- when, in fact, there were something like 37 migration events.

Another example was the formula that was used in the spreadsheet to count tilted filters counted "tilted filter" but not "filter tilts." So sometimes the text had been entered in a reverse fashion. And maybe I got that backwards, I don't know, but that's the idea.

So there were several mistakes like that that I discovered. They all led to underestimates of the counts of events for these filters.

Q. The underestimates were for which filters?
A. So for the Bard filters. I mean, for the Recovery and G2, G2X, Eclipse filters.
Q. Did you find any such errors when you analyzed the data for the SNF?
A. I did not. So the SNF has almost -- has very few events, and I did not see errors there.
Q. Okay. Let's move on to your third analysis, the migration bench test analysis.

Can you describe what you did there?

A. Yes. So for that, I was provided with data from an experiment that measured resistance, so a measure of resistance in millimeters of mercury. And the -- it was measuring -- so the factors in the experiment were -- so it looked at Recovery, the Recovery device, and it looked at the SNF device. And it did so at two different temperatures, 37 Celsius and 40 Celsius.

MR. MANKOFF: And can we look at trial Exhibit 2063?

2063. Can we see page 2?

BY MR. MANKOFF:
Q. Is this the test that you're describing?
A. These are the data that I used, yes.

MR. MANKOFF: I move for admission of trial Exhibit 2063.

MS. HELM: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit No. 2063 admitted into evidence.)

MR. MANKOFF: May we publish?

THE COURT: Yes.

MR. MANKOFF: Can you blow that up, please?

BY MR. MANKOFF:

Q. And did you analyze whether temperature had an effect in these data?

A. Yes. So what I did was, given the data that were available to me, basically what I had were the device, and so that's encoded in the sample ID, so RF for Recovery filter or Recovery; and the outcome measure of interest is this pressure at filter migration, which I understood to mean a resistance measure. So that's here.

And then temperature was another factor that was included here, so here on this page you see 37 degrees Celsius, plus or minus 2. And down below, if we look further, we would see 40 as the other temperature.

And then finally, there's tube diameter, but there's no variation in this. So for every entry here, the diameter is 28. So there was nothing I could look at with respect to 28, since every unit here was at diameter 28.

THE COURT: We're going to stop here and take the afternoon break. We will resume at 3:00 p.m.

Please remember not to discuss the case, and we'll

excuse the jury.

(Recess taken, 2:45 p.m. to 3:01 p.m.)

THE COURT: You may continue.

BY MR. MANKOFF:

Q. Before the break, we were looking at the migration test data. My question is, did -- when Bard increased the temperature to run the test, did that have an effect on the migration resistance of the filters?

A. Yes, it did.

Q. And what effect -- what direction was that effect?

A. So I actually don't remember. May I look at my -- so I know it changed the average pressure or resistance by nine units.

MR. MANKOFF: Can you zoom in to the full page, please.

BY MR. MANKOFF:

Q. Does the data summary refresh your recollection about --

A. Oh, yes. So increasing the temperature by 3 degrees increased the average resistance or pressure. Here, it's seen by about six units. In the model, the fancier model that I fit, it was more like nine units.

Q. And was that increase statistically significant?

A. Yes. It was highly significant.

Q. Which means what?

A. Which means the p-value, if I remember correctly, was

certainly less than 0.01. I think it was 0.004.
Q. But in laymen's terms, what does that mean?
A. It means that there is very strong evidence that this difference between 45.2, as you see here, and 51.5, the average resistance for -- of the two temperature levels, 37 versus 40, is real and not due to chance alone and that the true difference is -- the true difference in pressure is not zero.
Q. And you also then looked at the Recovery filter compared to the SNF filter overall; correct?
A. That's correct.
Q. And was the result of that analysis consistent with the other two analyses that we've gone over?
A. Yes, it was.
Q. Okay. So I'd like to now back up and discuss your overall conclusions about Bard's failure predictions. And if you need to refresh your recollection, you can turn to Exhibit 2447.
THE COURT: Is there a question?
BY MR. MANKOFF:
Q. Do you have that report in front of you?
A. So that exhibit is one of my reports?
Q. Right. That's the report involving Bard's failure predictions.
A. Okay. Yes, I have that in front of me.
Q. And so what was your overall conclusion with respect to the G2X and Bard's predictions of penetration?

MS. HELM: Objection, Your Honor. He's asking her to read from her report.

THE COURT: Yeah.

Dr. Betensky, you have to testify from memory. If you need to refresh your memory, say so. You can look at the document, set it aside, and then testify from memory. But you can't read from the document.

THE WITNESS: Okay. I need to refresh my memory, please.

THE COURT: What's the question?

BY MR. MANKOFF:

Q. The question is, what was Bard's overall prediction for G2X with respect to penetration compared to the Simon Nitinol filter?

THE COURT: You can look at the document.

THE WITNESS: Okay. Thank you.

Okay. Put it aside and --

BY MR. MANKOFF:

Q. Do you need the question again?

A. No. I got the question.

So the prediction that Bard made with respect to G2X versus SNF with respect to penetration was that G2X would always -- that they assigned G2X a greater than or equal to likelihood of penetration overall between -- so as compared to SNF.

And with respect to at least one category, they assigned the G2X a considerably increased level of likelihood of a particular penetration event -- penetration event as compared to SNF.

Q. And can you quantify the considerable increase?

A. Over 10 times.

Q. Okay.

A. Maybe much more. I just don't remember the number.

Q. Okay. So a similar question: What was Bard's overall prediction with respect to the G2X compared to the Simon Nitinol filter with respect to fracture?

A. I'm going to refresh my memory for a moment.

So with respect to one category of fracture, the estimate was one to four times higher for G2X as compared to SNF.

Q. And I have the same set of questions for Bard's predictions for the Eclipse. Were they -- how do they compare?

A. So those -- they were the same. So the comparisons are the same as what I told you for G2X versus SNF.

Q. In other words, they're higher than SNF, the same as G2X?

A. Right. So the Eclipse -- so Bard predicted higher likelihoods of those events, the penetration event -- penetration overall, a particular penetration event, and a fracture event at much higher levels for Eclipse as compared to SNF.

Q. Okay. Now, turning back to the failure reports, now that we've gone into the details about how you derive those numbers, can you tell us what you found for filter fracture for the Recovery filter for the May 2011 time period?
A. Can we look at that, please?
Q. Yes. So if you need to refresh your recollection, I would direct you to Exhibit 4498.
A. Which is my report?
Q. Yes.
A. Okay. So, I'm sorry, can you please ask the question again?
Q. So what was your prediction for the Recovery for filter fracture for May 2011?
THE COURT: You said Recovery?
MR. MANKOFF: Yes.
THE WITNESS: Okay. So for May 2011, the risk -- the reporting risk ratio for Recovery versus SNF was 56. So in other words, 56 times the risk for that fracture event for Recovery as compared to SNF.
BY MR. MANKOFF:
Q. Okay. And for the G2 filter, can you tell us what your result was for the December 2010 time period, just before Mrs. Hyde got her filter, for filter fracture?
A. Okay. I need to look at my report again.
Q. Okay.

A. I just -- yeah. So, I'm sorry, you said G2 or G2X?
Q. Yes. The G2 for December 2010 for the event of filter fracture.
A. So that reporting risk ratio is 7.1, so 7 times the risk for G2 as compared to SNF for filter fracture.
Q. And do you have data for the G2 going forward through 2014?
A. May I check?
Q. Yes.
A. Okay.
Q. Well, let me ask it this way: Did you have an estimate for G2 filter fracture for December 2011?
A. Okay. Yeah. So actually, so I do have estimates. I did have data from those years, so 2011, '12, '13, and '14. And those risk ratios are on the order of 7, 8, 9, 10 over those years. In other words, 7 or 8 or 9 or 10 times the risk of that event for G2 as compared to SNF.
Q. Okay. And did you have an estimate for the risk of caval perforation for --

So let me ask this first: Did you do a combined analysis involving the G2 and the G2X?
A. Yes, I did.
Q. And did you do an analysis for caval perforation for July 2010?
A. I'm going to check.

Okay, yes. So for caval perforation for July 2010,

for G2 combined with G2X, that reporting risk ratio is 18. So 18 times the risk for G2 or G2X as compared to SNF.

Q. And Bard had a category called migration plus embolization. Did you calculate a ratio for that event for July 2010?

A. For the combined G2?

Q. G2/G2X.

A. Let me check.

Yes. And for that category, so migration plus embolization, that risk ratio is 35. So 35 times the risk for G2/G2X combined as compared to SNF.

Q. And what about when you combine G2 and G2X and looked at fracture for 2010 through 2014? What values did you find there?

A. Let me check.

I'm sorry, I lost your question. Can you repeat that, please?

Q. So the combined reports for G2 and G2X, the filter fracture analysis.

A. Okay. So for that, I have a reporting risk ratio of 6, so 6 times the risk for G2/G2X versus SNF.

Q. And what was the trend from 2011 through 2014?

A. Also similar, level 6, 7, 8, 9. Maybe slightly increasing, but certainly holding at that level of risk ratio.

Q. And then turning to the Eclipse, did you do an analysis for July 2010 for Eclipse migration?

A. Yes, I did. And the reporting risk ratio was 20 in that case.
Q. And what was the result for caval perforation?
A. Risk ratio of 5.
Q. And then as of December 2011, what was your analysis for Eclipse filter fracture?
A. A reporting risk ratio of 2.9.
Q. And did that -- did you also look at a trend from 2012 through 2014?
A. Yes. And it appeared pretty stable, going from 4 to 5 to close to 6.
Q. Now, did Bard do analyses similar to this failure reporting analysis that we were just discussing?
A. In part, they did.
Q. Okay. What part?
A. So I've seen a document, a spreadsheet in which they calculated these relative risks or risk ratios. I'm using those terms interchangeably. But they just provided the estimates. They did not -- they did not conduct any statistical analysis or quantify the actual precision of the estimates or the information contained in the estimates.
Q. Are your results here consistent with the results that you saw?
A. I believe -- actually, is it possible to see those results?
Q. Well, I do have --

MR. MANKOFF: Can we pull up trial Exhibit 1940?

I would move to admit trial Exhibit 1940 into evidence.

MS. HELM: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit No. 1940 admitted into evidence.)

MR. MANKOFF: May we publish?

THE COURT: You may.

MR. MANKOFF: Can we zoom in to the bottom table?

BY MR. MANKOFF:

Q. Now, I don't think this was the analysis you were just referring to, but is this a similar analysis to what you did?

A. So this would be an earlier stage in my analysis. So what Bard has done here is they've reported the rates, they call them rates, of these events, fracture and migration, et cetera.

I did not report the rates separately. Instead, I reported the ratios of the rates because I was interested and was asked to compare filters.

So this is -- that analysis could be done on these data, but it wasn't done directly here. So...

Q. But are these -- is this analysis consistent with your analyses?

A. So it's absolutely consistent in terms of the approach. So the approach, meaning taking -- calculating risk as number of failures divided by number of sales. And you can see that in

this leftmost column where they've listed numbers of sales, and you can see that they're taking in numbers of events up from this table above.

So their approach is exactly the same as mine, using events divided by sales. They just haven't carried it as downstream as I have.

Q. Now, based overall on this -- all three analyses, have you come to an overall conclusion?

A. Yeah. So -- so this is an issue of, you know, of patient safety. And so given that patient safety is the matter of consideration here by the company, given a couple of things -- so given the very large magnitudes of these risk ratios that I've shown you, given their consistency across events that we've looked at, given the support from the additional experiments such as the bench testing, all of that together, even if the data are not as perfect as in an ideal world we'd like them to be, they're certainly concerning enough because they impact, you know, patient health, patient safety, that they should be paid -- should have been paid very, very close attention to and certainly follow-up studies should have been conducted at least.

Q. Are all of the opinions you've given here today to a reasonable degree of scientific certainty?

A. Yes.

MR. MANKOFF: No further questions at this time, Your

Honor.

THE COURT: Cross-examination?

MS. HELM: Thank you, Your Honor.

CROSS-EXAMINATION

BY MS. HELM:

Q. Good afternoon, Dr. Betensky.

A. Good afternoon.

Q. My name is Kate Helm. And I'm going to confess before I start, I don't have a graduate-level education in statistics.

The first thing I want to do is I want to try to make sure that I understand that you were asked to do three different things; correct?

A. Correct.

Q. Okay. One thing you were asked to do was to take a look at Bard's design failure mode effects analysis for different filters and compare them; correct?

A. Correct.

Q. The second thing you were asked to do was to take certain adverse event rates, where you took adverse events and divided it by sales and came up with a rate number; correct?

A. I wouldn't call that a rate. I'd call that a risk or a proportion.

Q. Okay. And you did that for the Simon Nitinol, and then you did it for the Recovery, the G2, the G2X, and the Eclipse; and for each of those retrievable filters, you compared it back to

the Simon Nitinol. Correct?
A. Correct.
Q. Okay. And the third thing you were asked to do was take a look at a specific bench test; correct?
A. Correct.
Q. Okay. At one point, you said Bard did not provide certain information. And I want to make sure it's very clear to everyone: All of the information that you received to conduct your analysis in this case came from the plaintiffs' attorneys; correct?
A. Correct. All of the underlying data, yes.
Q. And what you were asked to do in this case was to use the Simon Nitinol as your basis for each of your comparisons; correct?
A. Yes.
Q. You didn't choose the Simon Nitinol, did you?
A. No.
Q. It was chosen for you?
A. Yes.
Q. Okay. Do you know anything about the Simon Nitinol filter?
A. I do.
Q. And do you understand that it's a permanent filter?
A. I do.
Q. And do you understand that the Recovery, the G2, the G2X, and the Eclipse are what are called either optional or

retrievable filters that can be retrieved percutaneously?
A. I understand that at various points they were cleared for retrievability, and they may or may not be retrieved.
Q. Okay. And so you understand that those filters have a different utility than the Simon Nitinol; correct?
A. Perhaps potentially.
Q. Okay. And you also know, don't you, that the Simon Nitinol has been on the market since the early 1990s?
A. Yes.
Q. You're aware of that; correct?
A. Yes, although my understanding is that it's not currently on the market but --
Q. But that filter, that permanent filter, was on the market starting in the early 1990s; correct?
A. Yes.
Q. And I want to ask one quick question. You said certain data, that you found some mistakes, and you explained what I find to be the very complicated process of switching back and forth between spreadsheets. Those kind of mistakes, those are common. They're clerical mistakes and easy to make; correct?
A. They're easy to make.
Q. Thank you.
Okay. Let's start with the bench test.
A. Although, may I amend my answer to that, please?
Q. Sure.

A. Some of them are easy to make. Some of them, it's not quite clear how they could have been made; if a formula should have been in a cell, how it came to be hard coded as a zero. That is less understandable than if a formula doesn't quite capture all of the text within a box.
Q. Okay. Let's talk about the bench testing, okay?
A. Sure.
Q. You're not an engineer?
A. No.
Q. You've never designed an IVC filter?
A. Correct.
Q. You've never tested an IVC filter?
A. Correct.
Q. You've never established test protocol or set up a test for an IVC filter; correct?
A. Correct.
Q. Okay. And what you did in this report was you provided analysis between certain migration testing of the Recovery filter versus the Simon Nitinol filter; correct?
A. Well, the data were a pressure or resistance measure, which as I understand it is related to migration.
Q. Okay. And you were -- you were provided the data and simply asked -- and I'm not saying that what you do is simple by any means, but you were simply asked to do the comparison; correct?

A. I was asked to analyze the data.
Q. Okay. And you were not asked to review fatigue testing, were you?
A. No.
Q. And you were not asked to review radial strength testing, were you?
A. No.
Q. And you were not asked to review hook strength testing, were you?
A. No.
Q. And you were not asked to evaluate animal study tests, were you?
A. No.
Q. And you weren't asked to review corrosion resistance testing, were you?
A. No.
Q. And the test that you were asked to review, do you understand that that was a test -- you said pressure, and it was a test to evaluate cranial migration testing; in other words, movement of the filter up?
A. I didn't know to that level of detail what kind of migration.
Q. But it was a test for a Recovery filter; correct?
A. It was a comparison between Recovery and SNF.
Q. Okay. And for this Recovery testing you reviewed, you

reviewed data conducted at 40 degrees Celsius; correct?
A. And 37.
Q. Okay. And you didn't actually review test data at 37 degrees; you actually converted to 37 degrees. Correct?
A. No. I don't think so. I think the raw data were included from both levels of temperature.
Q. Okay. Do you understand in this case that Ms. Hyde did not have a Simon Nitinol filter?
A. Yes.
Q. Do you understand in this case that Ms. Hyde did not have a Recovery filter?
A. Yes.
Q. Okay. And you didn't analyze any testing relating to a G2X filter, did you?
A. No.
Q. And you didn't analyze any testing relating to an Eclipse filter, did you?
A. No.
Q. Okay. And do you know -- have you been provided information to show that there were dimensional changes and design changes between the Recovery filter and the G2X and the Eclipse filter?
A. I know that anecdotally.
Q. Okay. And were you made aware that the width of the legs of the G2X and the Eclipse filter are 40 millimeters?

A. No.
Q. And were you made aware that the width of the legs of the Recovery filter are 32 millimeters?
A. No.
Q. And would you agree with me that a comparison of 40 millimeters to 32 millimeters is approximately 25 percent wider?
A. That's correct.
Q. Okay. And you didn't do any analysis of the wider filter compared to the SNF on this specific test, did you?
A. I'm sorry, which is the wider filter?
Q. The G2X or the Eclipse.
A. Do you mean the bench tests?
Q. Yes, ma'am.
A. No. I didn't have that data.
Q. That wasn't provided to you?
A. Correct.
Q. Okay. Let's talk about DFMEAs for a minute.

A DFMEA, you learned recently, correct, is a mechanism used by engineers to evaluate a product; is that right?
A. Yes.
Q. And, in fact, when you were -- gave a deposition in July of 2016, you didn't even know what a DFMEA was, did you?
A. No.
Q. So since July of 2016, you've been provided with a number

of Bard's DFMEA's; is that correct?
A. Yes.
Q. And, again, you're not an engineer; correct?
A. I'm not an engineer.
Q. Okay. And you have never created a DFMEA; correct?
A. Correct.
Q. And you have never been asked to evaluate a product and put those predictions that you found and talked about in a DFMEA; correct?
A. Correct.
Q. Are you aware that a DFMEA is not a static snapshot? It's not a one-shot, one-time analysis?
A. I think I'm vaguely aware of that.
Q. Okay. And are you aware that through the development and actually through the life of a product, the DFMEA analysis can change based on information received by the engineers?
A. Yes.
Q. And you didn't take that into consideration; you used finite time periods for the DFMEAs. Correct?
A. I used what was provided.
Q. What was provided to you by the plaintiffs' attorneys; right?
A. Yes.
Q. Okay. And the DFMEAs that we talked about today were dated somewhere around 2004 to 2007; right?

A. They were from pretty close to the launch dates of the G2 and the Eclipse, which would have put them a little bit later than that, yes.
Q. But by that time, the Recovery filter had been on the market for well over 10 years; correct? I'm sorry. I misspoke.
By that time, the Simon Nitinol filter had been on the market for well over 10 years; correct?
A. Yes.
Q. And you weren't asked to look at earlier versions of the Simon Nitinol DFMEA, were you?
A. I looked at the Simon Nitinol filter DFMEA from 2006, which is what was available.
Q. Okay. You didn't look at any earlier versions --
A. No.
Q. -- of the Simon Nitinol to see how the engineer -- if the engineer's analysis had changed, if they had changed the failure modes, if they had changed the predictive rates. You didn't look at any of that, did you?
A. No.
Q. And you made a point of saying that the Simon Nitinol only had migration, where the retrievable filters had either caudal or cranial migration. Do you remember that testimony?
A. I think the -- there was different terms, the cephal- --
Q. Cephalad or --

A. Yes.
Q. -- cranial migration?
A. That's -- so, and I don't know about all of the retrievable. I was just looking at the G2s and the Eclipse.
Q. Okay. And you don't know what analysis the engineers went through to include those categories on the DFMEAs and why those categories were different for different filters, do you?
A. No.
Q. You simply took the broad categories of, for example, migration versus migration and looked at the numbers they predicted and the outcomes they predicted and compared them; correct?
A. Where I could. I mean, in some cases the migration was broken down.
Q. And you did that without any understanding as to how they got to those numbers, how they got to those conditions, or how they got to their analysis; correct?
A. Well, I had the vague -- I mean, the overall high-level understanding that those were the categories that were important as they were launching the product. Those were the categories for which they needed to consider failure.
Q. But, again, you weren't privy and you don't know what their analysis or process was in creating the DFMEAs; correct?
A. I know that they reviewed their prior data or their prior-to-current data to come up with the estimates.

Q. Okay. And, again -- and this is a -- this is not a statistical word, but your bogey, your comparison every single time was against the Simon Nitinol filter; correct?
A. Yes.
Q. Which is a permanent filter that cannot be retrieved percutaneously; correct?
A. My understanding was that it could be retrieved if it -- if necessary.
Q. But it wasn't designed to be retrieved?
A. Correct.
Q. Okay. Let's talk about, now, your third category, which I think you called -- and I want to make sure I got it right -- you called a reporting risk ratio.
A. Yes.
Q. Is that the term you used?
A. Those are the estimates that I provided.
Q. Okay. And you've been very careful to say that you are not calculating rates; correct?
A. Correct.
Q. Okay. But what you're calculating is a comparison of the adverse events of the Simon Nitinol filter versus the -- versus adverse events for the retrievable filters, and you're creating a risk ratio; correct?
A. Not quite. Because I'm not just comparing the numbers of events. I'm dividing them by the numbers of sales.

Q. Okay. Fair. Fair.

So you're taking the number of events for the Simon Nitinol for a finite period of time, you're dividing it by the sales for that period of time, and you get a number; correct?

A. Correct.

Q. And then you're doing that same analysis for the G2X; correct?

A. Correct.

Q. And then you're looking to see how they relate to one another; correct?

A. I'm calculating the ratio of those.

Q. Okay. Which is a comparison of the Simon Nitinol to the G2X or the Eclipse or the G2; correct?

A. Correct.

Q. Okay. You talked a little bit ago about making sure you took into consideration data inconsistencies and errors.

Do you remember that?

A. Yes.

Q. Okay. And I had the benefit of reading your report, and in the section of your report, you point out various problems or errors --

A. Sorry.

Q. It's okay. These things get us all.

-- you point out several problems or errors in the data you reviewed; correct?

A. Yes.
Q. Okay. And you set about to resolve or fix any errors; correct?
A. In some cases, I did.
Q. Okay. We talked a few minutes ago, the Simon Nitinol filter was available as early -- in the early 1990s; correct?
A. Yes.
Q. Okay. And you didn't consider any data on the Simon Nitinol filter or any adverse events against sales for the Simon Nitinol filter prior to 2000; correct?
A. The data sheets that I had started in 2000.
Q. Okay. And when you did your analysis, were you aware that the Simon Nitinol filter had been on the market for several years prior to 2000?
A. Yes.

And, actually, I should amend what I said. And subsequently I -- to my reports, I did find -- or I was provided with some data prior to 2000. But it was very sparse, and I did some analyses, and it didn't really change anything.

I also was aware even at the time that even though it may have been cleared for use in 1990 or thereabouts, there was no death until 1997 was my understanding.

MS. HELM: Your Honor, may we approach?

THE COURT: Yes.

(At sidebar on the record.)

MS. HELM: I don't know how -- she just referred to death.

THE COURT: For the Simon Nitinol.

MS. HELM: Okay. All right. I apologize. I --

THE COURT: I don't think -- that wasn't a Recovery --

MS. HELM: I overreacted.

THE COURT: -- cephalad migration death.

MS. HELM: I overreacted.

THE COURT: Okay.

(End of discussion at sidebar.)

THE COURT: Thank you.

BY MS. HELM:

Q. You don't have complete data before 2000 for the Simon Nitinol; correct?

A. Correct.

Q. And in the analysis you did, and in the spreadsheets and the risk ratios -- I'm being very careful -- that you created, you did not include any information about pre -- that you showed to the jury today, you didn't include any information about pre-2000 events for the Simon Nitinol; correct?

A. So I need to -- I want to be careful in answering this.

So there actually was a document from Bard that I saw that listed numbers of events and numbers of sales since launch through 2011, and SNF was on that list. And those numbers were very similar for fracture -- I think the data were just for

fracture. Those were very similar to what I had used, so that leads me to believe, again, that perhaps I did have close to what the data were since launch.

Q. But you didn't include any pre-2000 Simon Nitinol numbers in those -- in the data that you've shown to the jury today; correct?

A. So, no, not quite. My other answer to that is that the sensitivity analysis that I had mentioned previously, in which I added, you know, five events to all SNF categories of failure, isn't correct. It's not precise -- in that it's not precise. But that also could potentially address that point.

Q. Okay. These events that you referred to, these are adverse events that were reported to Bard about its filters; correct?

A. I'm not sure if they were all reported to Bard or if some were reported to the FDA and then retrieved by Bard -- not to use that word, but, you know, downloaded by Bard. So I'm not exactly sure how they got to Bard --

Q. Okay.

A. -- whether directly or through the FDA database.

Q. Okay. So there are two potential sources for your -- for these adverse events: One is directly reported to Bard, and two is events that were reported in the FDA database, called the MAUDE database, which Bard looked at and took into its analysis. Correct?

A. There perhaps are other sources as well.

Q. But those are at least two of the sources; right?
A. I mean, ultimately, the source for me was Bard.
Q. Okay. And you would agree with me that an adverse event can be asymptomatic? In other words, someone can have an adverse event and not know it; correct?
A. It's possible.
Q. And you would agree to me that depending on a patient's healthcare and what's going on with them, it may or may not -- an asymptomatic adverse event may or may not be detected; correct?
A. Correct.
Q. And you didn't do anything in this case to control for the possibility that there are more reports for the G2X or the Eclipse as opposed to the Simon Nitinol because those are retrievable filters, did you?
A. Well, one thing that I know from reading some reports is that even among the retrievable filters, many of them, if not most of them, are not retrieved and are left in.
Q. Yeah, I understand that, ma'am.

My question was, you didn't take into account either the asymptomatic nature or the fact that it may be a different course of treatment for a patient who has a retrievable filter; correct?
A. Well, the interpretation takes that into account.
Q. Okay. You didn't go back and look into patient files or

adverse event files to determine whether the event that was reported was asymptomatic, whether it was found incidentally, whether it had caused the patient any pain. You didn't do any of that, did you?

A. No.

Q. You just simply took the numbers; correct?

A. I took the numbers.

Q. Okay. Dr. Betensky, you've been hired by plaintiffs' attorneys who have filed lawsuits against Cook Medical, haven't you?

A. Yes.

Q. And that's another manufacturer who manufactures IVC filters; correct?

A. Yes.

Q. Okay. And you've been retained to them -- by them to do a similar analysis and to testify in litigation against Cook; correct?

A. The gist of the analyses are similar, not identical.

Q. And unlike this case, in the Cook cases you went back and actually read narratives to provide some background on the reports you analyzed, didn't you?

A. Yes.

Q. And one thing you did in Cook, in the Cook litigation, was you attempted to look at this retrieval bias, whether a retrievable filter made a difference or not, didn't you?

A. Yes.
Q. You have not done that here, have you?
A. No.
Q. And what you did was actually, you went back and looked at adverse event reports, reviewed narratives, and excluded from your calculations with Cook were adverse event reports were first discovered at the time the filter was retrieved; correct?
A. When they would have been asymptomatic.
Q. Right. So if it was asymptomatic, found incidentally at retrieval or for some other reason, you excluded those; correct?
A. I don't think it had to be at retrieval.
Q. Okay. If they were asymptomatic, you excluded them; correct?
A. Correct.
Q. In the numbers that you evaluated for the plaintiffs' attorneys in this case, you did not exclude any asymptomatic numbers because you didn't have that information to make that evaluation; correct?
A. I was not provided that data.
Q. Okay. And you never asked for it, did you?
A. No.
Q. So in those numbers that you provided today, in the risk ratio that you provided today, you have no idea how many of those patients were asymptomatic, whether the finding was

incidental, whether the finding was made at the time the filter was retrieved. You have no idea about any of that, do you?
A. Well, I have some idea from my work in Cook, in which I found that the results held up and were essentially the same when I did that analysis. And so that makes me feel some confidence that the same would hold true here.
Q. And you're aware that the FDA cautions against making comparisons of reports of adverse events between one filter to another filter. You're aware of that, aren't you?
A. That's one caution that they make.
Q. Okay. And, in fact, you cited in your report a publication where the FDA specifically says that it -- you should exert extreme caution when making an analysis of the reports of adverse events between one filter and another filter?
A. That's one quote from among many in that report.
Q. And you're also aware that the FDA has said that MAUDE data -- which is adverse event data; correct?
A. MAUDE data is adverse events.
Q. MAUDE is the database --
A. Yes.
Q. -- where adverse events are reported; right?
And that MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse events occurrences across devices. You're aware of that, aren't you?

A. Yes, though they suggest using it if nothing else is available.
Q. But they caution against it; correct?
A. Yes.
Q. Because it's not reliable; correct?
A. It's not as reliable as other sources of data, if they were available, would be.
MS. HELM: Thank you. That's all I have.
THE COURT: Redirect?
MR. MANKOFF: Yes, please.
Your Honor, before I start, may we approach?
THE COURT: Yes.
This will get better as we go on through the trial, ladies and gentlemen.
(At sidebar on the record.)
MS. HELM: I just want to make sure the record reflects that I didn't ask for this one.
THE COURT: I'm aware of that.
MS. HELM: This is his bean, not mine.
MR. MANKOFF: Yes, I'm using a bean.
MR. LOPEZ: I eat my beans.
THE COURT: We're going to follow the one-counsel rule here, counsel.
MR. LOPEZ: Okay.
THE COURT: I see you stepping up close, Mr. Lopez.

Go ahead.

MR. MANKOFF: So Dr. Betensky was asked --

THE COURT: Talk into the mic.

MR. MANKOFF: -- about asymptomatic events and whether she did anything to account for that. And she did look at the severity of the events, because severe events, you would expect to be reported. And this gets into filter embolization deaths.

So I believe the door has been opened to then ask her about that.

THE COURT: Ask her about what?

MR. MANKOFF: About whether -- what she did to account for the potential for asymptomatic events. A filter embolization death is not going to be asymptomatic, and that's her opinion.

THE COURT: So what is she going -- what is it you want to elicit from her?

MR. MANKOFF: That the rates for that event did not differ -- there was no trend across different adverse events that showed that there was a difference because of an event being potentially asymptomatic versus not asymptomatic.

But I don't know how to bring that out without bringing up this particular event.

THE COURT: I'm still not following you. Tell me what she would say.

MR. MANKOFF: She would say that she looked at the --

those numbers that she calculated, the reporting risk ratios for filter embolization death and compared them fracture -- some of the other events, fracture and perforation. And because they were consistent, her conclusion is that the asymptomatic potential of some of the events was not a factor in her analysis.

THE COURT: So are you saying specifically to deal with the subject of asymptomatic --

MR. MANKOFF: Yes.

THE COURT: -- events, she looked at death data and compared it to other adverse events to see if there was a difference which would be accounted for by asymptomatic events, and she couldn't find a difference?

MR. MANKOFF: Correct.

THE COURT: All right.

MS. HELM: Your Honor, I don't think I opened the door. I asked her about whether she took into account that the numbers came from asymptomatic events. That was my question, was you didn't take into account that these were asymptomatic events.

And she said, "No, I didn't. That information wasn't provided to me."

I don't see how that opens the door to a caudal migration or cranial migration, cephalad migration Recovery death. Because I didn't ask her if she compared -- if she

tried to compare asymptomatic versus symptomatic. I just said did you look at -- at adverse event reports and determine.

THE COURT: Well, but the clear implication of your questioning was that asymptomatic events are going to be discovered more often in retrievable filters than in the SNF, and therefore, the numbers are going to be higher for retrievable filters than the SNF. Right?

MS. HELM: That --

THE COURT: Isn't that the point you wanted to make?

MS. HELM: Yes, but that's not the question I asked.

THE COURT: But that's clearly the message you were communicating.

MS. HELM: But I didn't ask the question that you just articulated about the comparison or did she take it in. I just simply stopped with, you didn't take into consideration asymptomatic events.

THE COURT: But --

MR. MANKOFF: My answer --

THE COURT: Hold on.

MR. MANKOFF: Sorry.

THE COURT: But the point you were making to the jury is that the data for retrievable filters is skewed in favor of reporting events because they find more asymptomatic events when they remove filters. That's what I understood you to be saying.

MS. HELM: Well, yes, and actually my point was that she didn't take that into consideration.

THE COURT: But what I understand is being said is she did look into that.

MS. HELM: Well, she said no.

THE COURT: Well, she didn't look -- she had no way to tell what was an asymptomatic versus symptomatic event in retrievable filters, but it sounds like she tested for asymptomatic event bias by looking at events that couldn't be asymptomatic, mainly deaths, and didn't find that bias and therefore concluded it wouldn't exist for other events either. It sounds like that's what she did.

MR. MANKOFF: Right. So the question was did she do anything to take this into account, and the answer is yes, she did. But she couldn't answer that because she's under orders not to bring it up.

THE COURT: Well, did she do this for all filter categories?

MR. MANKOFF: It was --

THE COURT: I mean, all filter types.

MR. MANKOFF: So the -- because there are -- because the filter embolization reports relate to the Recovery, she used that filter. Is that your question?

THE COURT: So the data she was looking at was Recovery filter migration deaths?

MS. HELM: Exactly.

MR. MANKOFF: Compared to --

THE COURT: SNF filter migration deaths.

MR. MANKOFF: Compared to Recovery fracture and Recovery perforation and Recovery. So she can extend that comparison and draw conclusions about all of the events.

THE COURT: So what you would have her testifying about are Recovery filter migration deaths?

MR. MANKOFF: Right. But her -- but her response applies to all of the filters and all of the events.

THE COURT: Have you talked to her about a way to elicit this testimony without mentioning deaths?

MR. MANKOFF: No. And if you say that the door has been opened, I don't know how I would elicit it because she wouldn't know that.

THE COURT: Well, it seems to me you could have prepped her to say that she looked at severe categories of events that would not have been asymptomatic and compared them to those that would be asymptomatic, and she didn't find a difference.

But I take it she's not -- she hasn't been clued in to something like that. In other words, the only way you can cover it now is to have her describe Recovery filter migration deaths.

MR. MANKOFF: Which she won't do because she doesn't

know she's allowed to.

THE COURT: Well, but if you --

What are you saying?

MR. LOPEZ: I'm just trying to help, Judge.

THE COURT: You're violating the two-lawyer rule. Go ahead.

MR. LOPEZ: I know.

We'd have to spend a few minutes with her because we weren't prepared with her. We told her not to do it, so --

THE COURT: Right. Well, so we'd have to take a break.

It seems to me, Ms. Helm, that if she did something to try to control for the very point you were making, it's fair for her to be able to explain it. It also seems to me that there's a way to explain it without describing Recovery filter migration deaths.

And so I'm inclined to take a five-minute break, let you all talk to her about the way she can describe it without talking about Recovery filter migration deaths, but to make the point she tested for severe events that wouldn't have asymptomatic bias and found it was the same as those that might.

So that's my conclusion is we ought to do that. We'll take a five-minute break, and you can walk through that with her so that when she gets on the stand, she can describe it

without mentioning Recovery filter migration deaths.

MR. MANKOFF: Thank you, Your Honor.

MS. HELM: Thank you.

(End of discussion at sidebar.)

THE COURT: Ladies and gentlemen, thanks for your patience. I don't want to keep you sitting there for another few minutes. We're going to take just a five-minute break to finish up the issue that we're talking about. We're going to only go till 4:30, so we'll get you back in here at 4:00 o'clock or two minutes after 4:00, and we'll go for another half hour.

But why don't I go ahead and excuse you for five minutes, and then we'll come get you in just a moment.

(Recess taken, 3:54 p.m. to 4:02 p.m.)

THE COURT: Let's continue.

REDIRECT EXAMINATION

BY MR. MANKOFF:

Q. Dr. Betensky, with respect to reports for retrievable filters versus permanent filters, did you analyze serious adverse events to come to a conclusion about that effect?

A. Yeah. So I did -- I did do one analysis where I -- I -- so I was interested in trying to figure out how the reporting risk ratio, which are the very large numbers that you've seen, how those relate to a true risk ratio if we didn't have any problems of reporting or detection such as we've been

discussing.

And so mathematically, I wrote down a relationship between that true risk ratio, which is what we'd all like to know, and how that relates to the reporting risk ratio. And it's absolutely true that it's affected by potential differences in reporting rates, differences in detection rates, which could be due to retrievability versus permanence, for example.

But then it occurred to me that under certain assumptions, if that true risk ratio were equal to 1, meaning no difference in risk between two filters, if that true risk ratio were 1, then we couldn't see the variation in the reported risk ratios that we're seeing.

So if you remember from that spreadsheet with the yellow highlighting, going -- each row was a comparison, let's say, between G2X and SNF or Recovery and SNF. If you went across rows and looked at the different failure events, they weren't constant. They weren't even approximately constant. They varied quite a bit.

And based on the math that underlies that, that suggests that even with differential reporting and even with differential detection, which might be the case due to a permanent device versus a retrievable device, that could -- if the true -- so, sorry -- if the true risk ratio were 1, we couldn't see that variation.

And being a statistician, I didn't want to rely just on the estimates again, so I tested statistically whether those estimates of the reporting risk ratios did differ across events. And from a statistical point of view, not just from the raw number point of view.

And I did this analysis for the Recovery versus the SNF, and they were indeed, for some of the comparisons among the failure types, they were indeed statistically significantly different from each other, which leads me to conclude that my original assumption that the true risk ratio is 1 couldn't be true. In other words, that risk -- that true risk ratio, even with all of this -- these differential reporting and detection aside, that true risk ratio has to be greater than 1.

Q. And what do you mean by "true risk ratio"? How does that relate to filter failures?

A. So the true risk ratio would be the risk ratio applied to, you know, to a huge population prospectively.

Q. So is the true risk ratio, would that be the failures if you had perfect information?

A. Correct. Or -- yes. Complete information, yes.

Q. With respect to the documents you reviewed and where you got them from, did you have the opportunity to ask the lawyers for additional information if you needed it?

A. Yes.

Q. And did you get everything that you felt you needed in

order to do these analyses?
A. I felt I -- my understanding was that I received everything that was available that I could use, yes.
Q. There were some questions about the dates or the -- Bard's failure prediction documents, what dates they related to. Did those documents reflect Bard's knowledge at the time of the documents?
A. So my understanding is that those documents reflected the knowledge -- their knowledge at the launch of the G2, G2X, and Eclipse, and the current -- their current knowledge of the probabilities of these occurrences at those contemporaneous times. So at that 2006 period, what they understood the SNF risks of occurrences to be.
MR. MANKOFF: Can we pull up Exhibit 614, please?
I believe this is in evidence. May we publish?
THE COURTROOM DEPUTY: It's not in.
THE COURT: We don't show it in evidence.
BY MR. MANKOFF:
Q. Is this one of the documents that you relied on in doing your adverse event analysis?
A. I believe I may have used this in the analysis that I did, some of which we discussed earlier, on the through May 2011 comparisons.
MR. MANKOFF: I move for admission of Exhibit 614.
MS. HELM: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit No. 614 admitted into evidence.)

MR. MANKOFF: May we publish?

THE COURT: You may.

BY MR. MANKOFF:

Q. There were some questions about whether you had evaluated any data regarding the SNF before 2000, and you mentioned a document. Is this the document you're referring to?

A. Yes, it is.

Q. And what does it tell you about the SNF data?

A. So according to this document, SNF data are provided from the time of its launch, so I guess approximately 1990, and it lists the number of fracture complaints as eight and the number of units sold as 80,187.

Q. And can you indicate where you're seeing that it's from launch?

A. Up here. That's where it states it's from launch.

Q. Now, there were -- going back to the potential issue of asymptomatic events, if there are events like we're seeing on the screen here that are asymptomatic, would they show up in these reports?

A. That would depend if they were detected or not.

Q. So what about an event that's -- has not caused any symptoms and has not been detected?

A. Then that's not here.

Q. And if that were the case for the G2X or the Eclipse filter, how would that influence your results?
A. So that would -- so their absence decreases the rates. So -- or let me say it the other way around. If those events had been captured, that would produce larger rates than what are here.

MR. MANKOFF: No further questions.

THE COURT: All right. Thank you, Doctor. You can step down.

(Witness excused.)

MR. LOPEZ: Your Honor, we're going to start a deposition that we won't complete, but --

THE COURT: A video deposition?

MR. LOPEZ: Video deposition.

THE COURT: All right. Ladies and gentlemen, let me mention something.

Ms. Reed Zaic, you can come on up.

Some of these depositions you are going to see have the witness looking at and testifying about documents that we're using in the trial, but at the time the depositions were taken, they've been assigned different numbers than we're using here in the trial. And I know it sounds like you should be able to anticipate that, but litigation doesn't work that way.

So what we're going to do when we get to a deposition where there's a trial exhibit being discussed with a different

number, is at the start of the deposition we'll tell you what the deposition number is and the corresponding trial number. So that will at least help you in your notes know which trial exhibit is being testified about. I think there's only four or five on this one.

MS. REED ZAIC: Five.

THE COURT: Some, there may be a longer list that we'll actually hand you so you can keep track in your notes of what the trial exhibits are. And we will also, when we get to the start of the deposition, have the exhibits moved into evidence so you know that what the witness is testifying about in the deposition is a trial exhibit that has come into evidence.

MS. REED ZAIC: This is the background summary of Dr. Murray Asch.

Dr. Murray Asch is an interventional radiologist with 30 years of experience in the field of interventional radiology. He is a board -- he is board certified in interventional radiology. He graduated from the University of Western Ontario with his medical degree in 1983.

In 1999, Dr. Asch received funding from Nitinol Medical Technologies and C.R. Bard for a study called "Initial Human Use of the Recovery Retrievable IVC Filter." He served as the principal investigator of that study, a retrievability study involving 58 patients in Toronto, Canada.

And the exhibits that will be displayed during the video are numbers 202, which will be trial Exhibit 552; Exhibit 203, which will be trial Exhibit 553; Exhibit No. 212 will be trial Exhibit 561; Exhibit 218 will be trial Exhibit 563; and Exhibit 223 will be trial Exhibit 567.

We'd like to move those exhibits into evidence now, Your Honor.

THE COURT: Any objection?

MS. HELM: I'm sorry, Your Honor. I missed the first two. Do you mind rereading those?

THE COURT: The first two were 552 and 553.

MS. HELM: Thank you, Your Honor. No objection.

THE COURT: All right. So trial Exhibits 552, 553, 561, 563, and 567 are admitted.

(Exhibit Nos. 552, 553, 561, 563, and 567 admitted into evidence.)

THE COURT: And we can play the deposition.

Sounds like we don't have any sound.

MS. REED ZAIC: May we start that over, Your Honor?

THE COURT: Yeah, please. But let's turn it up even louder if we can.

(Video deposition played.)

THE COURT: Let's pause it for just a minute.

Ladies and gentlemen, can you hear it?

JURY MEMBER: It's hard, but yeah.

THE COURT: Let's see if we can make that sound better.

(Video deposition played.)

THE COURT: Let's stop there.

All right. Members of the jury, we're going to break until tomorrow morning. We plan to see you at 9:00 o'clock. We'll excuse you at this time.

(Jury not present.)

THE COURT: Counsel, how is the time on the Asch deposition being divided?

MS. REED ZAIC: She's looking.

MR. LOPEZ: She's looking right now.

MS. SMITH: It's -- can you hear me?

THE COURT: Yeah, I can hear you.

MS. SMITH: 37 minutes and 55 seconds for plaintiffs, and 15 minutes and 26 minutes for defendants. And -- sorry, 15 minutes and 26 seconds for defendants.

And how do we take care of the joint designations? 50/50? Okay.

MR. LOPEZ: It's a minute and a half for each on the joint.

MS. HELM: Your Honor, it's 39 minutes for the plaintiffs and 17 minutes for the defendants.

MR. LOPEZ: Yeah.

THE COURT: Okay. Give me just a minute here.

All right, counsel. As of the end of today, plaintiffs have used 8 hours and 58 minutes; defendants have used 4 hours and 47 minutes.

And we will plan to see you tomorrow morning at 8:30. I've got a call now that I need to take.

MR. ROGERS: Thank you, Your Honor.

MR. LOPEZ: Thank you, Your Honor.

That was through Asch; right? In other words, calculating all of Asch into --

THE COURT: No. Actually, what I did, just to balance it out, there was actually 17 minutes of Asch we played. I gave that all to the defendants in this, meaning the 39 minutes of Asch we play tomorrow will all go to you.

MR. O'CONNOR: Got it.

MS. HELM: Understood. Thank you, Your Honor.

(Proceedings adjourned at 4:35 p.m.)

C E R T I F I C A T E

I, JENNIFER A. PANCRATZ, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 21st day of September, 2018.

s/Jennifer A. Pancratz
Jennifer A. Pancratz, RMR, CRR, FCRR, CRC